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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,284	02/15/2002	Kazuaki Sasaki	H&A-107	9039

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EXAMINER	
LEACH, CRYSTAL I	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/075,284	SASAKI ET AL.	
	Examiner	Art Unit	
	Crystal I. Leach	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on May 23, 2006.

Response to Arguments

Applicant's arguments filed on May 23, 2006 have been fully considered but they are not persuasive. Rosenchein et al. '558 disclose that an operator applying ultrasound to a subject may watch or listen to a display from the microphone in order to determine whether cavitation is occurring (col.8, lines 18-31). The operator is listening to audible sound detected by humans, which would therefore be in the human acoustic frequency range of 20 Hz to 20 kHz. The added limitations of "said audible sound having a frequency from 250 to 550 Hz" are encompassed in the human acoustic frequency range.

In regard to a "unit which detects a point of time of detection of the audible sound using a cross-correlation function," examiner refers applicant to pp. 3, line 2-3 of the previous office action. Rosenchein et al. '558 fully disclose a unit (microphone) that detects audible sound that correlates to the occurrence of cavitation in the region of interest (col. 8, lines 18-31), and therefore detects audible sound at the point in time that cavitation occurs. Examiner refers applicant to pp.3, lines 8-13 of the previous office action, which addresses cross-correlation function between waveforms of detected and typical audible sound. Ueberle et al. give a full disclosure regarding audible sound and cross-correlation function (col. 1, lines 55 - col.3, line 7). As stated in the previous office

action (pp. 4, lines 6-8), FFT analysis is a functional equivalent to the waveform analysis taught by Ueberle et al. '621.

Applicant contends that the motivation to combine Rosenchein et al. and Ueberle et al. do not provide or suggest the effect of audible sound being produced or detected when generated bubbles are expanded to burst or destroy tissue in the affected area or region of interest. Examiner notes that motivation need not be explicitly disclosed in the secondary reference but rather what the prior art as a whole teaches to one of ordinary skill in the art at the time of the invention (see MPEP 2143.01). Medical ultrasound cavitation is the destruction or destroying of tissue in a region of interest by melting or boiling of tissue which causes formation of bubbles and subsequent bursting of the formed bubbles. The formation and burst of the bubbles causes audible sound which can be detected with a microphone as disclosed by Rosenchein et al. (see col. 8, lines 18-31 as also described in the previous office action).

Examiner upholds previous rejections dated February 23, 2006 from previous office action provided below. Rejection to added limitations is also included.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4, and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenchein et al. US Patent No. 6,113,558 view of Ueberle et al. US Patent No. 4,819,621, hereinafter Ueberle et a1.'621, both of record.

Rosenchein et al.'558 teach setting a therapeutic transducer to operate at a continuous mode insonation in order to maintain cavitation at a region of interest to be treated (see col. 3, lines 62-67 and col. 4, lines 1-34) while the operator is allowed to watch or listen (see col. 5, lines 4-19) from a display and/or a microphone and determine whether cavitation is occurring under the desired conditions (col. 7, lines 60-67 and col. 8, lines 1-31). The ultrasonic transducer is capable of coagulating tissue as the treatment includes the frequency of 1000 KHz (1MHz) (col. 5, line 28). The microphone provides a detected audible sound, which is correlated with the occurrence of cavitation (col. 8, lines 18-31). Additionally, the operator is listening to audible sound detected by humans, which would be in the human acoustic frequency range of 20 Hz to 20 kHz. Therefore, the microphone is capable of detecting and relaying audible sound in the range of 20 Hz to 20 kHz, which encompasses the range of 250–550 Hz.

Rosenchein et al.'558 do not expressly teach a waveform analyzing unit which obtains a cross-correlation function between a waveform of the detected audible sound and a typical waveform of an audible sound previously obtained in a region to be treated as an indication of the occurrence of cavitation.

In the same field of endeavor, Ueberle et al.'621 teach a waveform analyzing unit which obtains a cross-correlation function between a waveform of the detected audible sound and a typical waveform of an audible sound previously obtained in a region to be

treated as an indication of the occurrence of cavitation (see col. 1, lines 55- col. 3, line 7; referring to a test signal or typical waveform being cross-correlated with the reception signal or the detected audible signal in order to determine the occurrence of cavitation by waveform comparison).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Rosenchein et al.'558 by utilizing the waveform analyzing unit of Ueberle et al. '621 as an alternative functional equivalent of detecting the occurrence of cavitation. In other words, rather than detecting just a sound as taught by Rosenchein et al.'558, detecting a comparative sound which nonetheless functions in the same manner of providing an indication that cavitation is occurring.

Furthermore, Ueberle et al.'621 teaches that the detection from the waveform analyzing unit can be linked to a control signal which can be further utilized (see col. 4, lines 31-44).

Therefore, it would also have been obvious to one skilled in the art at the time that the invention was made to have utilized the control signal to stop, alter or continue treatment based on the treatment protocol of interest. Rosenchein et al.'558's protocol teaches the maintenance of cavitation (see col. 3, lines 62-67 and col. 4, lines 1-34). Therefore, the control signal as taught by Ueberle et al.'621 could be utilized to maintain cavitation treatment.

Finally, use of FFT analysis would have been an alternative waveform analysis for detection of a comparative signal in order to identify the occurrence of cavitation.

Therefore, the FFT analysis is a functional equivalent to the waveform analysis as taught by Ueberle et al.'621.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Martin et al.'499 (US Patent No. 6,007,499) wherein in col. 14, lines 11-13, it is stated that coagulation occurs at 0.5-20 MHz which includes frequencies even lower than 1 MHz capable for coagulation of tissue.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal I. Leach whose telephone number is 571-272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CIL

S. THOMAS HUGHES
SUPERVISORY PATENT EXAMINER
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